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TRANSMITTAL FORM (to be used for all correspondence after	U.S. Paters are required to respond to a collection Application Number Filing Date First Named Inventor Art Unit Examiner Name	PTO/SB/21 (08-0 Approved for use through 08/30/2003. OMB 0651-003 ent and Trademark Office; U.S. DEPARTMENT OF COMMERC tion of information unless it displays a valid OMB control number 10/763,498 01/22/04 Andrew R. Marks 1614 to be assigned				
Total Number of Pages in This Submiss	on 24	Attorney Docket Number	5199-139			
<u></u>	ENC	LOSURES (Check all that	t apply)			
Fee Transmittal Form Fee Attached Amendment/Reply After Final Affidavits/declaration(s Extension of Time Request Express Abandonment Reque Information Disclosure Statem Certified Copy of Priority Document(s) Response to Missing Parts/ Incomplete Application Response to Missing F under 37 CFR 1.52 or	st Remai	Drawing(s) Licensing-related Papers Petition Petition to Convert to a Provisional Application Power of Attorney, Revocation Change of Correspondence Addre Terminal Disclaimer Request for Refund CD, Number of CD(s)	ess to to Ap	Technolopeal Co Appeals peal Co peal Not oprietary atus Lett ner Enclentify bel	osure(s) (please low):	
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Firm or Individual name Signature Date 9/24/04 Todd Holmbo, Reg. No. 42,665 Date Todd Holmbo, Reg. No. 42,665						
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sufficient postage as first class mail in the date shown below.						
Typed or printed name Ping Xiao			·			
Signature	ingli	'ao		Date	9/24/04	

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Andrew R. Marks, et al.,

Docket No.:

5199-139

Serial No.:

10/763,498

Examiner:

to be assigned

Filed:

January 22, 2004

Group Art Unit: 1614

Title:

NOVEL ANTI-ARRYTHMIC AND HEART FAILURE DRUGS THAT TARGET THE LEAK IN THE RYANODINE RECEPTOR

(RyR2)

September 24, 2004

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.97(b)

Sir:

In accordance with the duty of disclosure under 37 CFR §1.56, applicant hereby notifies the U. S. Patent and Trademark Office of the following documents, which are listed on the attached PTO/SB/08A and PTO/SB/08B forms. The examiner may deem these documents to be relevant to patentability of the claims of the above-identified application. A Copy of the document is enclosed for the examiner's convenience.

The submission of the listed documents is not intended as an admission that any of the documents constitute prior art against the claims of the present application. Applicants do not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

Applicants respectfully request that the listed documents be considered by the examiner and be made of record in the present application and that initialed copies of forms PTO/SB/08A and PTO/SB/08B be returned in accordance with MPEP §609.

It is understood that no fee is necessary for submission of this Information Disclosure Statement, as it is being filed before the later of three months from the filing date or the mailing of the first Office Action on the merits. The Commissioner is hereby authorized to charge payment of any fees associated with this application or credit any overpayment to Deposit Account No. 02-4270.

Respectfully submitted,

Todd Holmbo

Reg. No. 42,665

Attorney for Applicants

BROWN RAYSMAN MILLSTEIN

FELDER & STEINER LLP

163 Madison Avenue

P.O. Box 1989

Morristown, New Jersey 07962-1989

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PTO/SB/08A (08-03)

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Substitute for form 1449/PTO

Sheet 1

TRADEMAN

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

of 2

Complete if Known				
Application Number	10/763,498			
Filing Date	01/22/04			
First Named Inventor	Andrew R. Marks	- "		
Art Unit	1614			
Examiner Name	to be assigned			
Attorney Docket Number	5199-139			

			U. S. PATENT	DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ² (# known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
<u>-</u>		^{US-} 6489125	12-03-2002	Marks, et al.	
•		^{US-} 5910494	06-08-1999	Brieaddy	
		^{US-} 5859240	01-12-1999	Brieaddy	
		^{US-} 5817652	10-06-1998	Brieaddy, et al.	
		^{US-} 5723458	03-03-1998	Brieaddy, et al.	
		^{US-} 5580866	12-03-1996	Housley, et al.	
		^{US-} 5416066	05-16-1995	Kaneko, et al.	
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		^{US-} 20030134331	07-17-2003	Marks, et al.	
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		^{US-} 10/608,723	03-11-2004	Marks	
		^{US-} 10/288,606	07-17-2003	Marks, et al.	
		^{US-} 09/568,474	03-11-2004	Marks	
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	FORE	IGN PATENT DOCU	IMENTS		
 Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
	Country Code ³ Number ⁴ Kind Code ⁵ (if known)	MM-DD-YYYY		Or Relevant Figures Appear	T ⁶
	WO03034980	05-01-2003	Picariello, T.,	113 of 4665 pages	
	WO02053548	07-11-2002	Nagase T.,	<u> </u>	
	WO02051838	07-04-2002	Weller T.,		
	WO02051232	07-04-2002	Sifferlen T.,		
	WO0100185	01-04-2001	Kilpatrick C.,		
	WO9703986	02-06-1997	Tanaka H.,		П

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Signature	Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form	1449/PTO	Complete if Known		
		Application Number	10/763,498	
INFORM	ATION DISCLOSURE	Filing Date	01/22/04	
		First Named Inventor	Andrew R. Marks	
	ENT BY APPLICANT	Art Unit	1614	
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oot 2	of 2	Attorney Docket Number	5199-139	

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Examiner Initials*	Cite No.1		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Whe Relevant Passages or Releva	
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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)	MM-DD-YYYY		Or Relevant Figures Appear	T
		WO9212148	07-23-1992	Kaneko N.,		
		JP11199574	07-27-1999	Harada K.,		
		JP10045706	02-17-1998	Kano H.,	-	
		JP3093419	04-18-1991	Kabumoto K.,		
						Г

Examiner	Date	
Signature	Considered	

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der the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. TRADE Stitute for form 1449/PTO Complete if Known **Application Number** 10/763,498 **Filing Date** INFORMATION DISCLOSURE 01/22/04 STATEMENT BY APPLICANT **First Named Inventor** Andrew R. Marks Art Unit 1614 (Use as many sheets as necessary) **Examiner Name** to be assigned Attorney Docket Number Sheet 19 5199-139

		NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
		Alvarez et al., "Late post-myocardial infarction induces a tetrodotoxin-resistant Na (+) current in rat cardiomyocytes."			
		J. Mol. Cell Cardiol 32: 1169-1179, 2000			
		Antos et al., "Dilated cardiomyopathy and sudden death resulting from constitute activation of protein kinase A."			
		Circ. Res., 89: 997-1004, 2001			
		Barbone et al., "Comparison of right and left ventricular responses to left ventricular assist device support in patients with severe heart failure:	·		
		a primary role of mechanical unloading underlying reverse remodeling."			
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		Bennett et al., "Identification and characterization of the murine FK 506 binding protein (FKBP) 12.6 gene."			
		Mamm. Genome, 9: 1069-1071, 1998			

Examiner	Date	
Signature	Considered	

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¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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Substitu	Substitute for form 1449/PTO		Complete if Known		
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INF	ORMATION	DIS	CLOSURE	Filing Date	01/22/04
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Sheet	2	of	19	Attorney Docket Number	5199-139

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		Beuckelmann et al., "Intracellular calcium handling in isolated ventricular myocytes from patients with terminal heart failure."	
		Circ., 85: 1046-1055, 1992	
		Brillantes et al., "Stabilization of calcium release channel (ryanodine receptor) function by FK506-binding protein associated with the calcium	
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		like domain."	
-		J. Biol. Chem., 272: 27582-27588, 1997	

Examiner	Date	
Signature	Considered	

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5199-139

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Attorney Docket Number

19

Sheet

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Catsoulacos, "Synthesis of substituted dihydrobenzothiazepines and related compounds."	
		J. Heterocyclic chemistry 7(2): 409-411, 1970 (N/A)	
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		EMBO J., 16: 3866-3876, 1997	
		Chidsey et al., "Augmentation of plasma norepinephrine response to exercise in patients with congestive heart failure."	
		N. Engl. J. Med., 267:650, 1962	
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		Daoud et al., "Effect of verapamil and procainamide on atrial fibrillation-induced electrical remodeling in humans."	
		Circulation, 96: 1542-1550, 1997	

Examiner	Date	
Signature	Considered	

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Substitu	Substitute for form 1449/PTO			Complete if Known		
Cabonia	10 10/10/11/17/40/1			Application Number	10/763,498	
INF	ORMATION	DIS	CLOSURE	Filing Date	01/22/04	
STA	TEMENT E	BY A	PPLICANT	First Named Inventor	Andrew R. Marks	
	(Use as many she	ats as n	ecessarv)	Art Unit	1614	
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Sheet	4	of	19	Attorney Docket Number	5199-139	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Eichhorn and Bristow, "Medical therapy can improve the biological properties of the chronically failing heart. A new era in the treatment of	
		heart failure."	
		Circulation, 94: 2285-2296, 1996	
		Elvan et al., "Pacing-induced chronic atrial fibrillation impairs sinus node function in dogs: electrophysiological remodeling."	
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:		Fabiato, A., "Calcium-induced release of calcium from the cardiac sarcoplasmic reticulum."	
		Am. J. Physiol., 245: C1-C14, 1983	
		Falk, R.H., "Atrial fibrillation."	
		N. Engl. J. Med., 344: 1067-1078, 2001	

Examiner	Date	
Signature	Considered	

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Substitute for form 1449/PTO

Complete if Known

Application Number 10/763,498

INFORMATION DISCLOSURE Filing Date 01/22/04

STATEMENT BY APPLICANT First Named Inventor Andrew R. Marks

Art Unit 1614

Attorney Docket Number

Examiner Name

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		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		Fodor, et al., "New convenient synthesis of 1,4-benzothiazepines."	
		Tetrahedron Letters. 36(5): 753-756, 1995 (N/A)	
		Fozzard, H. A., "Afterdepolarizations and triggered activity."	
		Basic Res. Cardiol., 87: 105-113, 1992	
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CODOLINA				Application Number	10/763,498		
INF	ORMATION	DIS	CLOSURE	Filing Date	01/22/04		
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Sheet	6	of	19	Attorney Docket Number	5199-139		

		NON PATENT LITERATURE DOCUMENTS	
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	:	Gomez et al., "Defective excitation-contraction coupling in experimental cardiac hypertrophy and heart failure."	
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		Hachida et al., "Protective effect of JTV519, a new 1,4-benzothiazepine derivative, on prolonged myocardial preservation."	
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			Application Number	10/763,498	
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Cuamina	Cita	NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		Hain et al., "Phosphorylation modulates the function of the calcium release channel of sarcoplasmic reticulum from cardiac muscle."	
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-		protein Kinase C in rat ventricular myocardium."	
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		Ito, et al., "JTV-519, a novel cardioprotective agent, improves the contractile recovery after ischemia reperfusion in coronary perfused guinea pig	
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		Br. J. Pharmacol. 130 (4): 767-776, 2000	
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		Kawabata et al., "Effect of a novel cardioprotective agent, JTV-519, on metabolism, contraction and relaxation in the ischemia-reperfused	
		rabbit heart."	
		Jpn Circ J. 64: 772-776, 2000	
		Kawabata et al., "A novel cardioprotective agent, JTV-519, is abolished by nitric oxide synthase inhibitor on myocardial metabolism in ischemia-	
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		Kiriyama et al., "Effects of JTV-519, a novel anti-ischaemic drug, on the delayed rectifier K+ current in guinea-pig ventricular myocytes."	
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		pericarditis model."	
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		Marks, A. R., "Cardiac intracellular calcium release channels: role in heart failure."	:
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		J. Cell Physiol. 190(1): 1-6, 2002	
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		Reiken et al., "Beta-adrenergic receptor blockers restore cardiac calcium release channel (ryanodine receptor) structure and function in	
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Substitu	te for form 1449/PTO			Complete if Known		
Cabalita	to for form 144on 10			Application Number	10/763,498	
INF	ORMATION	DIS	CLOSURE	Filing Date	01/22/04	
STA	TEMENT E	BY A	PPLICANT	First Named Inventor	Andrew R. Marks	
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Sheet	17	of	19	Attorney Docket Number	5199-139	

		NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				
		Szabo, et al., "Saturated heterocycles."				
		Canadian Journal of Chemistry. 65(1), 175-181, 1987	·			
-		Szabo, et al., "Synthesis and spectroscopic investigation of 1,4-benzothiazepine derivatives."				
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		Tse and Lam, "JTV-519 Japan Tobacco"				
		Curr. Opin. Investig. Drugs. 2(7): 936-939, 2001				

Examiner		Date	
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		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Valdivia et al., "Rapid adaptation of cardiac ryanodine receptors: modulation by Mg2+ and phosphorylation."	
		Science, 267: 1997-2000, 1995	
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		Am. Heart J., 106: 798-811, 1983	

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_		Yamamoto et al., "Abnormal Ca2+ release from cardiac sarcoplasmic reticulum in tachycardia-induced heart failure."	
		Cardiovasc. Res., 44: 146-155, 1999	
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